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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/725,955	11/30/2000	Marcel Bourrier	N1239	8639

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EXAMINER
IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
1638	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/725,955	Applicant(s) BOURRIER, MARCEL	
	Examiner Medina Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,23,25-28 and 31-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-19,25-28 and 31-34* is/are rejected.

7)☒ Claim(s) *1-5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' response of 06/26/02 has been entered. Claims 20-22, 24, 29-30 and 35 have been cancelled. Therefore, claims 1-19, 23, 25-28 and 31-34 are pending and are under examination. All previous rejections and objections not stated below have been withdrawn.

This Office action contains NEW GROUNDS OF REJECTION not necessitated by Applicants' amendments. Therefore, this action is non-final. The delay in applying these new grounds of rejection is regretted.

Objections

Claims 1 and 19 remain objected and dependents 2-18, 23, 25-28 and 31-34 are objected for failing to recite complete Accession information. The ATCC accession no must be filled in as appropriate, as stated in the last Office action.

The specification is objected to because of the following: The statement of deposit in the specification, page 23, does not comply with the deposit requirement set forth in 37 CFR 1.801-1.809. The deposit statement in the specification must be amended to include the deposit accession number.

Claim Rejections - 35 USC § 112, 2nd paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10, 14-28 and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8, " the cells or protoplasts of the tissue culture being from" is indefinite because the metes and bounds of "being from" are unclear. The claims should read ---the cells or protoplasts of said cells having been isolated from ---.

In claim 9, "capable of expressing" implies the plant may or may not express all the morphological and physiological characteristics of the inbred corn plant MNI1. It is suggested that "capable of expressing " be replaced with ---expresses---, for clarification.

In claims 9 and 10, " MNI1 should be followed by acccession no., for clarification. Also, "such a process" in claim 10 is indefinite and should be changed to --said process---.

Claims 10, 23 and 28 recite "utilizing" or "using" without any positive method steps by which one could practice the claimed method.

In claims 14 and 17-18, "said hybrid corn" should be changed to ---the hybrid corn---.

In claim 15,---and harvesting the resultant seed--- should be inserted before the period, for complete method steps.

Claims 19-24 remain rejected as the metes and bounds of what is retained in "MNI1-derived" corn plants or progeny is unclear. Applicants' arguments in page 4 of the response have been considered but are not found persuasive because one skilled in the art would not understand what is encompassed in the "derived" plants. If Applicants intend progeny of MNI1 corn plants, the claims should be recited as such. In addition, the end product of the method of claim 19 is "further MNI1-derived corn plants" and the method is directed to producing a "MNI1-derived" corn plant. Clarification is required.

In claims 25- 26, 31 and 33, the metes and bounds of "transgene" and "single gene conversion" are unclear as the term

or the phrase does not carry with it any limitations as to the structural or physiological properties of the gene.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "single gene conversion", in claims 31 and 33-34, is used by the claim to mean "moving a desired morphological and physiological characteristic via the backcrossing technique or via genetic engineering," (see page 8, paragraph 20 of the specification) while the accepted meaning is "a nonreciprocal event that occurs at or near the crossover point during reciprocal recombination." (see Darnell *et al* 1990, In Molecular Cell Biology, Scientific American Books, Inc. New York, New York, specifically page 478). The use of the term -- transgene -- would obviate this rejection.

Claim 26 is indefinite as the claimed method does not result in "a corn plant that contains its genetic material...transgenes" . Dependent claim 27 is included in the rejection.

Claims 27 is indefinite because it is unclear if "corn plants are produced in claim 26. In addition, the limitation "corn plants"

lacks antecedence in claim 26 which is drawn to a method for producing "a corn plant"

In claims 33-34, a " single gene conversion corn plant" of claim 31" lacks antecedence basis; also, "where" should be changed to --wherein---, for clarification.

Claim 34 recites improper Markush. The phrase "resistance to bacterial, fungal or viral resistance", in line 3, should be replaced with ---resistance to bacterial disease, resistance to fungal disease, resistance to viral disease--. Also, "corn endosperm, and improved nutritional quality" is indefinite. It is unclear if Applicant intends ---corn endosperm with improved nutritional quality---. Clarification is required.

Claim Rejections - 35 USC § 112, Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-28 and 31-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims are drawn to a corn plant or parts thereof of the inbred line MNI1 comprising a single gene conversion including transgenes, dominant or recessive alleles which confer specific traits, or which have been transformed so that its genetic material contains one or more transgenes operably linked to regulatory sequences. The claims are also drawn to a method for producing an F1 plant that contains in its genetic material a transgene by crossing a transformed inbred corn line MNI1 that contains the transgenes with an unidentified corn line or with a non-tranformed inbred corn line MNI1, and corn plants and parts thereof produced by said method.

Applicant has not disclosed or provided guidance for a transformed or non-transformed corn inbred line MNI1 or parts thereof comprising a single gene conversion that confers specific characteristics, wherein such characteristics were transferred by breeding techniques. No guidance has been provided for the obtention of F1 generation or subsequent generation corn plants that retain any morphological or physiological characteristics of the

inbred corn line MNI1, in addition to a single gene conversion or transferred transgenes.

While the transformation of a plant with a transgene that confers a desired trait such as herbicide resistance, insect resistance, resistance to pathogens, or male sterility, is well within the level of one skilled in the art, the state of the art teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genotypic background may be transferred into the genetic background of another plant to confer the phenotype in said different plant. For example, Hunsperger et al (US Patent No. 5, 523, 520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that didn't result in the expected transfer gene trait (column 3, lines 26-46). Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait, and that such effects are unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci,

and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15). See also, Eshed et al who teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effects are not common in corn breeding materials, such that one or more single gene traits can be transferred from one genetic background to another.

Therefore, given the lack of guidance in Applicants specification regarding single gene conversion in corn inbred line MNI1, the lack of guidance regarding the isolation of a multitude of non-exemplified transgenes or their evaluation in particular corn genetic backgrounds, the state of the art, the unpredictability inherent in single gene conversion, and lack of working examples, one skilled in the art would not be able to make a transformed corn inbred line MNI1 or parts thereof further comprising a single gene

conversion, or MNI1-derived plants including F1 and subsequent generation plants that retain any MNI1-derived morphological or genetic characteristics, without undue experimentation. Applicants should note that no single gene conversion plant or plants with any of the phenotype of claims 32 and 34 have been disclosed. Applicants should also note that one skilled in the art would not be able to make and/or use a corn plant or parts thereof that are not adequately described (see Written description rejection below).

Written Description

Claims 6, 12-14, 16-18, 25-28, 31-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the same reasons as set forth in pages 4 and 5 of the Office action of 03/26/02, for cancelled claims 22, 24, 30, and 35.

Claims 12-14, 16-18 are included in the rejection because Applicants has not disclosed any specific morphological or genotypic characteristics for the hybrid corn plants/seed produced

by crossing a MNI1 inbred corn plant with unidentified corn plants. Applicant only describes the inbred corn line MNI1 which has specific genotypic and phenotypic characteristics that distinguish the line from other corn lines. Absent any specific morphological or genotypic characteristics that distinguish F1 hybrid corn plants/seeds from other corn plants/seeds, one skilled in the art would know Applicants are in possession of the claimed invention at the time the application was filed. Claims 25-27 and 31-34 are included in the rejection because Applicant has not described a multitude of non-exemplified transgenes or single gene conversions, or their phenotypic effects in particular corn genetic backgrounds. In addition, the claims do not characterize the sequence or identity of the transgenes or the single gene conversion, or recite phenotypic effects (in claims 25-26, 31 and 33) of expression of the "one or more transgenes" or "single gene conversion" and therefore, the corn plants or plant parts transformed with or comprising said one or more transgenes, or a method for using or producing said plants and plant parts are not similarly described. Since Applicant has not described even F1 generation plants, methods for using F1 plants and subsequent

generation plants, as claimed in claim 19 and 23, are not similarly described. Applicants should note that because various breeding techniques and a multitude of uncharacterized breeding partners and breeding generations (claim 28) have been employed, substantial variation in structure and phenotype are expected among the resultant plants. Therefore, one skilled in the art would not recognize from the disclosure that Applicants are in possession of the invention as broadly claimed.

Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description Requirement published in Federal Registry/Vol. 66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Claim Rejections - 35 USC § 102/103

Claims 12-14, 16-18 and 25-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Foley (US Patent 5,973, 239, filed 12/04/1998(A)).

Foley disclosed an inbred corn plant/seed designated as LH265 and methods for producing a corn plant and seeds by

crossing the inbred corn line LH265 with itself or with another corn line as well as hybrid corn plant and seeds produced by crossing the inbred line LH265 with another corn line. Foley also disclosed the corn inbred line may further comprise a cytoplasmic factor that confers male sterility or may comprise a single gene conversion that will characteristics such as herbicide resistance, resistance to insects, resistance to bacterial diseases, fungal diseases, viral disease, or enhanced endosperm quality. The reference teaches a single gene converted plants and that the single gene can be dominant or recessive or a trangene. Since the prior art corn plant and the plant of the claimed invention share charateristics such as a cytoplasmic factor that confers male sterility or a single gene conversion that confer characteristics such as herbicide resistance, resistance to insects, resistance to bacterial diseases, fungal diseases, viral disease, or enhanced endosperm quality, the claimed progeny corn plants/seeds are expected to possess such characteriscs, especially since the second parents involved in the breeding processes are unknown. While the corn plant of Foley is designated as LH265 and the corn inbred line of the instant invention is designated as MNI1, there are insufficient identifying

characteristics set forth in the claims that distinguish the claimed corn plant from the prior art corn plant.

It would have been prima *facie* obvious to an ordinary plant breeder at the time of Applicants invention to use the method disclosed by Foley with any corn plants/seeds to produce corn plants/seeds with characteristics such as male sterility, herbicide resistance, resistance to insects, resistance to bacterial diseases, to fungal diseases, or to viral disease, or enhanced endosperm quality, with a reasonable expectation of success.

Therefore, the claimed invention is anticipated by or, in the alternative, is obvious over the prior art, absent evidence to the contrary.

Remarks

No claim has been allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The

Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

September 5, 2002
mai

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